Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

JUL - 6 2006

The assigned 510(k) Number is: K061139

Submitter's Name and Address

Bayer Healthcare LLC
511 Benedict Avenue
Tarrytown, NY 10591
Establishment Registration Number: 2432235

Contact Person: Andres Holle
Telephone: 914-524-3494
Fax: 914-524-2500
e-mail: andres.holle.b@bayer.com

Contract Manufacturer

Fisher Diagnostics
8365 Valley Pike
Middletown, VA 22645-0307
Establishment Registration: 1181121

Device Name:	ADVIA® IMS PSA Calibrator and ADVIA® IMS cPSA Calibrator
Proprietary/Trade Name	ADVIA® IMS PSA Calibrator and ADVIA® IMS cPSA Calibrator
Common Name:	Calibrator Material
Classification Name:	Calibrator
Classification:	Class II
Regulation Number:	21 CFR 862.1150
Panel:	Chemistry (75)
Product Code:	JIT

Predicate Device:

Lipoprotein Calibrator
Premarket Notification Number: K051619

Device Description:

The Bayer ADVIA® IMS PSA Calibrators and ADVIA® IMS cPSA Calibrators are for values of calibrator material prepared in bovine serum with non-serum constituents added.

The analytes currently in the calibrator material are:
PSA in the ADVIA® IMS PSA Calibrator
cPSA in ADVIA® IMS cPSA Calibrator

Intended Use:

For in vitro diagnostic use in the calibration of quantitative PSA assays on the ADVIA® IMS system.

For in vitro diagnostic use in the calibration of quantitative complexed PSA assays on the ADVIA® IMS system.

Substantial Equivalence:

The ADVIA® IMS PSA and cPSA Calibrators are substantially equivalent in intended use, storage and handling, stability, source material, and instructions for use as the previously cleared Bayer Lipoprotein Calibrators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 17 2006

Bayer Healthcare, LLC
c/o Mr. Andres Holle
Manager, Regulatory Affairs
511 Benedict Ave.
Tarrytown, NY 10591-5097

Re: k061139
Trade/Device Name: ADVIA® IMS PSA Calibrator and ADVIA® IMS cPSA Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: April 17, 2006
Received: April 25, 2006

Dear Mr. Holle:

This letter corrects our substantially equivalent letter of July 6, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

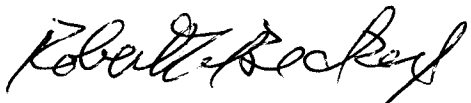
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0131. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3105 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Robert L. Becker, Jr., M.D., PhD
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061139

Device Name: ADVIA® IMS PSA Calibrator

Indications For Use:

For in vitro diagnostic use in the calibration of quantitative PSA assays on the ADVIA® IMS System.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Indications for Use

510(k) Number (if known):___K061139_____

Device Name: ADVIA® IMS cPSA Calibrator

Indications for Use:

For in vitro diagnostic use in the calibration of quantitative complexed PSA assays on the ADVIA® IMS system.

Prescription Use ___X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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